REMARKS

I. INTRODUCTION

Applicants appreciate the Examiner's participation in an interview with Applicants' attorney on August 11, 2010 (the "Interview"), and confirming that claims 142-146 are allowable if certain objections to these claims are addressed and these claims are rewritten in independent claim format. (See Interview Summary dated August 13, 2010).

Claims 83 and 103 have been cancelled above, without prejudice. Claims 68, 89, 113, 125 and 131 have been amended to clarify the subject matter recited therein. Claims 142-146 have been rewritten in independent form to include the subject matter of previously-pending independent claims 68, 89, 113, 125 and 131, respectively. Accordingly, claims 68-82, 84-102, 104-148 and 150-162 are still under consideration in the above-referenced application. Provided above, please find a claim listing indicating the amendments to claims 68, 89, 113, 125, 131 and 142-146, the cancellation of claims 83 and 103, and the status of other claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

Claims 83, 103 and 147 stand finally rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with an enablement requirement.

Regarding claims 83 and 103, while Applicants respectfully disagree with the Examiner's § 112 rejection of these claims, claims 83 and 103 have been cancelled herein

above without prejudice to expedite the prosecution of the present application. Accordingly, the rejection of claim 83 and 103 under 35 U.S.C. § 112, first paragraph is now moot, and should therefore be withdrawn.

With respect to claim 147, the Examiner alleges that the present application lacks the description or illustration of the recitation that **the optical fiber has an end portion that is provided at a position of an image plane of the at least one portion which is established by the lens**, as recited in this claim. In addition, the Examiner is apparently unclear regarding the meaning of the "position of an image plane."

Applicants respectfully assert that one having ordinary skill in the art would understand that the position of the image plane is a position of the focused radiation that provides an image. For example, as shown in Figs. 2A-2F in the present application (as also reproduced below with notations of the "IMAGE PLANE"), the image plane of the portion being imaged is provided at a position where the radiation (e.g., the image radiation) is focused by the lens 32, based on the recitations of claim 147. Thus, it becomes clear that these drawings, and other drawings in the present application (e.g., Figs. 4A and 4B) illustrate that the end portion of the optical fiber 14 is provided at the position of the image plane of the portion being imaged that is established by the lens 32.

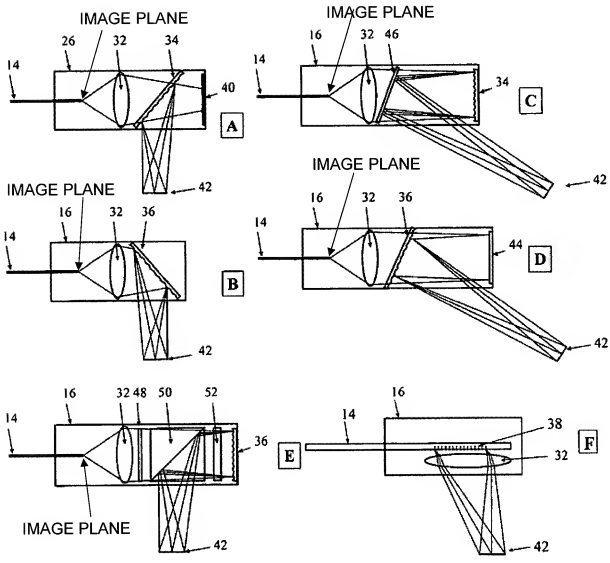

FIG. 2

Accordingly, at least for the reasons as set forth above, Applicants respectfully assert that the rejection of claim 147 under 35 U.S.C. § 112, first paragraph should be withdrawn.

III. OBJECTIONS TO CLAIMS 142-146 SHOULD BE WITHDRAWN

Claims 142-146 stand objected to as being allegedly unclear. In particular, the Examiner believes that it is unclear how the dispersive arrangement is structured to provide any number of resolvable points. (See Final Office Action, p. 4, last 3 lines).

Applicants respectfully disagree and assert that one having ordinary skill in the art would certainly understand (in view of the disclosure of the present application) that the number of resolvable points is equal to the bandwidth of the light source divided by the diffraction order. The variable relating to the dispersive arrangement is N, which is the number of gratings illuminated by the input beam. Since the diameter of the catheter is fixed, then this N number can be equal to the diameter of the catheter times the groove density of the grating (which is an intrinsic property of the grating) – that should to be specifically configured as described in the specification to achieve a particular number of the resolvable points.

Accordingly, it is clear that the dispersive arrangement is certainly structured to provide the number of resolvable points as recited in claims 142-146. Thus, for at least such reasons, the objection to claims 142-146 should be withdrawn.

IV. REJECTIONS UNDER 35 U.S.C. §§ 102(b) AND 103(a) SHOULD BE WITHDRAWN

Claims 68-75, 81, 82, 84-87, 89-95, 101, 102, 104-107, 109-116, 118-128, 130, 137-140, 147-157, 161 and 162 stand finally rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,318,024 issued to Kittrell et al. (the "Kittrell Patent"). Claims 83, 88, 103, 108, 117, 129, 131-136, 141, 146 and 158-160 stand finally

rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of U.S. Patent No. 3,941,121 issued to Olinger et al. (the "Olinger Patent"). Claims 76-78 and 96-98 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of International Publication No. WO 99/44089 by Webb et al. (the "Webb Publication"). Claims 79, 80, 99 and 100 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of U.S. Patent No. 5,275,594 issued to Baker et al. (the "Baker Patent"). Applicants respectfully assert that the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent, fails to teach, suggest or disclose the subject matter recited in independent claims 68, 89, 113, 125 and 131, and the claims which depend therefrom, for at least the following reasons.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Machinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual

determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the "TSM test"). *See In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit's application of the TSM test, *see KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; *see In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not

an automaton, constrained by a rigid framework. *Id.* at 1742. However, "the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. *See In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The Kittrell Patent describes a laser endoscope for generating a spectrally resolved spatial image of tissue. Fiber optics positioned within an optically shielded endoscope are used to deliver laser radiation to tissue to be imaged. Radiation returning through the fiber optics from the tissue is spectrally resolved and used to generate an image of tissue that can assist in diagnosis and treatment. (See Kittrell Patent, Abstract).

A generalized spectral system is shown in Figs. 21 and 22 of the Kittrell Patent. As illustrated in Fig. 21, an excitation light 95 is sent from a laser or conventional

light source into a selected optical fiber 20. This light passes through a beam splitter 52 or a mirror with a hole 50 (as shown in Fig. 22), and focused onto the input end 40 by a lens 41. The light exits the distal end of the optical fiber 20, passes through the optical shield 12, and impinges on the tissue 34 (of Fig. 4). The fluorescence and scattered light is returned via the same or a different optical fiber 20 to the proximal end 40 of the optical fiber 20. This return light 54 is separated by the beam splitter 52 or by the mirror 50 with hole 51 (see Fig. 22), and enters a spectrum analyzer 60. A diffraction grating 68 of the spectral detector 65 can disperse the return light from a target. The dispersed light is projected onto a multichannel detector 70 which has many detectors. (See *id.*, col. 19, lns. 20-47). Fig. 13B of the Kittrell Patent illustrates the use of a prism, but without any lens.

The Olinger Patent relates to a needle endoscope includes a hollow needle of about 18-gauge, a lens system within the needle, an image transmitting bundle of flexible fiber-optic rods within the needle, a plurality of illumination transmitting fiber-optic rods within the needle, an operative channel within the needle, and apparatus to shift the image transmitting bundle with respect to the lens system and needle to provide focus adjustment for focusing the endoscope on objects at various distances from the end of the needle. (See Olinger Patent, Abstract).

The Webb Publication relates to a scanning confocal microscopy system, especially useful for endoscopy with a flexible probe which is connected to the end of an optical fiber (9). The probe has a grating (12) and a lens (14) which delivers a beam of multi-spectral light having spectral components which extend in one dimension across a region of an object and which is moved to scan in another dimension. The reflected

confocal spectrum is measured to provide an image of the region. (See Webb Publication, Abstract).

The Baker Patent relates to angioplasty system and method for identification and laser ablation of atherosclerotic plaque at a target site in a blood vessel. Such system and method employ fluorescence analysis for identification of noncalcified plaque and calcium photoemission analysis for identification of calcified plaque. Calcified plaque is identified by time domain analysis of calcium photoemission. A high energy pulsed ultraviolet laser can be used for stimulation of fluorescence and for stimulation of calcium photoemission. The system is capable of distinguishing between calcium photoemission and a defective condition of optical fibers that are used to deliver laser energy to the target site. In an another embodiment of the angioplasty system, calcium photoemission is identified during a nonablative initial portion of the laser ablation pulse. When calcium photoemission is not identified, the laser ablation pulse is terminated during the initial nonablative portion thereof. (See Baker Patent, Abstract).

Applicants' invention, as recited in amended independent claim 68, relates to an apparatus for obtaining information associated with an anatomical structure which comprises, *inter alia*:

> **an image-forming lens arrangement which is configured to provide there through electro-magnetic radiation**; and
>
> **a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation** and **forward a dispersed radiation thereof to at least one section of the structure regarding which the information is being obtained on a macroscopic scale**, wherein **the image-forming lens arrangement forms an image of the anatomical structure**.

Applicants' invention, as recited in independent claim 89, relates to an apparatus for obtaining diagnostic information associated with an anatomical structure and modifying at least one property of at least one portion of the structure which comprises, *inter alia*:

> **an image-forming lens arrangement** and a plurality of fibers **configured to provide there through the electro-magnetic radiation, at least one first fiber of the fibers being configured to provide a first electro-magnetic radiation to the at least one portion of the structure regarding which the information is being obtained** so as to obtain the information, and at least one second fiber of the fibers configured to provide a second electro-magnetic radiation to the at least one portion so as to modify the at least one property; and
>
> **a dispersive arrangement configured to receive the first and second electromagnetic radiations,** wherein **the image-forming lens arrangement forms an image of the anatomical structure**.

Applicants' invention, as recited in independent claim 113, relates to an apparatus for obtaining information associated with an anatomical structure which comprises, *inter alia*:

> **an image-forming lens arrangement configured to provide a plurality of electro-magnetic radiations**, and **a dispersive arrangement configured to receive the electro-magnetic radiations** and **forward a dispersed radiation of each of the electro-magnetic radiations to at least one portion of the structure regarding which the information is being obtained** and at least partially overlap the at least one portion ..., wherein **the image-forming lens arrangement forms an image of the anatomical structure**.

Applicants' invention, as recited in independent claim 125, relates to an apparatus for obtaining information for an anatomical structure which comprises, *inter alia*:

> **an image-forming lens arrangement configured to provide an electro-magnetic radiation**, and **a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation and forward a dispersed radiation thereof to a particular**

> **location on at least one portion of the structure regarding which the information is being obtained** ..., wherein **the image-forming lens arrangement forms an image of the anatomical structure**.

Applicants' invention, as recited in independent claim 131, relates to an apparatus for obtaining information associated with an anatomical structure which comprises, *inter alia*:

> **an image-forming lens arrangement which is configured to provide there through electro-magnetic radiation**; and
>
> **a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation** and **forward a dispersed radiation thereof to at least one portion of the structure regarding which the information is being obtained** ..., wherein **the image-forming lens arrangement forms an image of the anatomical structure**.

Thus, each of amended independent claims 68, 89, 113, 125 and 131 recites (i) an "image-forming lens arrangement" and a "dispersive arrangement", that (ii) the radiation is forwarded to at least one portion of a "structure regarding which the information is being obtained", and that (iii) the image-forming lens arrangement forms an image of the anatomical structure.

First, Applicants respectfully assert that the Kittrell Patent fails to teach, suggest or disclose that **the image-forming lens arrangement forms an image of the anatomical structure**, as recited in amended independent claims 68, 89, 113, 125 and 131. In the Final Office Action and in the Advisory Action, the Examiner points to lens 41 in Figs. 21 and 22 of the Kittrell Patent as being equated to the image forming lens arrangement recited in independent claims. (See Final Office Action, p. 2, lns. 15-17 and Advisory Action, p. 2). As shown in Figs. 21 and 22 of the Kittrell Patent, the lens 41 forwards the radiation to a spectral analyzer 60. Thus, it appears that the Examiner

equates this spectral analyzer 60 with the dispersive arrangement, as recited in amended independent claims 68, 89, 113, 125 and 131. In the Advisory Action, the Examiner also contends that optical shield 12 of the Kittrell Patent can also act as a lens, and point to column 15, lines 13-14 of the Kittrell Patent in support of this contention. (See Advisory Action, p. 2).

However, even if the lens 41 of the Kittrell Patent can be equated to the recited lens, such lens 41 only forms an image of the fibers, and certainly not of the anatomical structure. In addition, the shield 12 of the Kittrell Patent does not form an image of anything, much less the anatomical structure. Thus, it is respectfully asserted that the Kittrell Patent lacks **the image-forming lens arrangement which forms an image of the anatomical structure**, as recited in amended independent claims 68, 89, 113, 125 and 131 of the present application.

Second, as previously stated, while the lens 41 of the Kittrell Patent may be image-forming, the radiation being forwarded to the spectral analyzer 60 is in no way **then forwarded to at least one section of any structure, much less regarding which the information is being obtained**. In summary, the configuration of *the image-forming lens providing the radiation to the dispersive arrangement which then forwards the dispersed radiation to the structure*, as recited in amended independent claims 68, 89, 113, 125 and 131, is in no way described or shown in the Kittrell Patent, much less in Figs. 21 and 22 thereof.

Third, as previously argued by Applicants, Figs. 13A-13F of the Kittrell Patent show that the transparent shield/enclosure 12 appears to have an equal distance between the inner surface and the outer surface along the section thereof through which the

radiation is exhibited. Thus, no image can be formed thereby. In addition, the lens 41 of the Kittrell Patent which forwards the radiation from a laser to the fibers 20 also do not provide or form any images, and thus cannot be equated to the "**image-forming lens arrangement**", as recited in amended independent claims 68, 89, 113, 125 and 131.

The Olinger Patent, the Webb Publication and/or the Baker Patent do not cure such deficiencies of the Kittrell Patent, and the Examiner does not contend that they do.

Accordingly, Applicants respectfully submit that the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent, does not render obvious the subject matter recited in independent claim 68, 89, 113, 125 and 131. The claims which depend from such independent claims are also not taught, suggested or disclosed by the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent for at least the same reasons.

Regarding claim 147, this claim depend from independent claims 74 and independent claim 68, and also recites that "**the optical fiber has an end portion that is provided at a position of an image plane of the at least one portion which is established by the lens**." In the Final Office Action, the Examiner contends that such subject matter is disclosed in the Kittrell Patent by stating that the lens arrangement 40 and 41 of such publication guides light into optical fibers. (See Final Office Action, p. 5).

However, the Kittrell Patent nowhere discloses that the optical fiber has **an end portion that is provided at a position of an image plane of at least one portion** of the anatomical structure which is established by the lens. Indeed, the alleged combination of the Kittrell Patent with any of the Olinger Patent, the Webb Publication and/or the Baker

Patent fails to teach or suggest the subject matter recited in this claim, at least for the reasons presented herein and in the prior response filed by Applicants on May 7, 2010.

Accordingly, Applicants respectfully request the Examiner to confirm that the subject matter of claim 147 is not taught, suggested or disclosed by the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent.

Thus, for at least these reasons, withdrawal of the final rejections of these claims under 35 U.S.C. §§ 102(b) and 103(a) is respectfully requested.

V. ALLOWABLE SUBJECT MATTER

Applicants gratefully acknowledge the Examiner's indication that claims 142-145 contain allowable subject matter, and would be allowed if rewritten in independent form to include the recitations of the claims from which they depend. (See Interview Summary dated August 13, 2010). As the Examiner shall ascertain, claims 142-146 have been rewritten in independent form to include the subject matter of previously-pending independent claims 68, 89, 113, 125 and 131, respectively. Accordingly, claims 86, 88 and 89 should be allowed.

VI. CONCLUSION

In light of the foregoing, Applicants respectfully submit that all pending claims 68-82, 84-102, 104-148 and 150-162 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

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